



4321 WASHINGTON, SUITE 2020, KANSAS CITY, MISSOURI 64111

{816} 531 6763 {800} 627 4360 {816} 531 4033 fax 5727 '99 JUN 30 P2:02

May 26, 1999

Dockets Management Branch (HFA-305)
The Federal Drug Administration
5630 Fishers LN RM 1061
Rockville, MD 20857-0003

Dear Sirs,

As a specialist in compounding pharmacy, I have several objections with Docket No 98N-1265.

Our pharmacy has specialized in compounding for 37 years, because the services we provide are in demand by physicians and their patients. Everyday we supply prescription medications to patients who would otherwise suffer with a less desirable alternative or, worse, no medication at all. And everyday we hear appreciation from the patients and physicians we serve.

It is at best arbitrary to limit our expertise to the state of Missouri, especially when the number of pharmacies with our expertise, experience and education is limited. Denying patient access to our expertise and forcing them to use untrained and inexperienced pharmacies clearly compromises optimum healthcare.

And the formula for restricting compounding is certainly capricious, since most of the prescriptions we dispense are custom-compounded for the individual patient.

Furthermore, we have filled prescriptions for physicians and their patients across the United States. This is not because we have sales representatives knocking on doctor's doors. This is simple testimony, by word of mouth, physician to physician and patient to patient, that we are skilled in the art of compounding and meet the needs of patients and physicians.

If anything is restricted, it should be pharmacies that attempt compounding without the proper training, materials, equipment and expertise. This sort of legislation underscores the FDA's lack of understanding, misplaced interference and poor judgement in pharmacy regulation, and begs the question of whether the FDA is working for the people they represent, or the interests of drug manufacturers.

Sincerely,

Kristy Timmons, RPh

98N-1265

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